

Framework for Assessing Non-occupational, Non-dietary (Residential) Exposure to Pesticides (Draft 12/22/98)



Pesticide - a compound used to control a pest. A pest can be an insect, plant or any organism such as a mold or bacteria.

Executive Summary

Non-occupational, non-dietary exposure assessment is an important component in establishing an individual's overall risk from pesticides. This type of assessment focuses primarily on those exposures that occur in and around the home (otherwise known as residential exposure assessment). It is important to note that exposures that occur as a result of pesticide applications in schools, parks and day care centers are included under the term "residential." Residential exposures are "non-dietary" in nature (i.e., through the skin or inhaled).

The importance of non-dietary residential exposure assessment has only increased with the passage of the Food Quality Protection Act of 1996 and the statute's increased emphasis on the protection of children. EPA is currently refining its assessments in order to improve overall quality and achieve more realistic exposure estimates. This paper discusses:

- ☐ exposure basics;
- ☐ how EPA currently conducts non-dietary residential exposure assessment;
- ☐ the generally conservative nature of the Agency's non-dietary residential exposure assessment; and
- ☐ how EPA is refining non-dietary residential exposure assessments.

Exposure Basics

Why Does EPA Regulate Pesticide Exposure?

The Agency's basic mandate is to protect the environment and to protect the general public from unsafe exposure to pesticides. Assessing the exposure a person might receive to a pesticide is a key component of making sure the person is protected.

Congress has passed three main statutes that require us to make sure that pesticides are used safely:

- ☐ The Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended in 1988;
- ☐ The Federal Food, Drug, and Cosmetic Act (FFDCA); and
- ☐ The Food Quality Protection Act (FQPA) of 1996 (which updates both FIFRA and FFDCA)

How are We Exposed to Pesticides?

Basically, we are exposed to pesticide residues through four ways:

- ☐ using a pesticide (including mixing it up and spraying it);
- ☐ eating food that contains pesticide residues;
- ☐ using drinking water that contains pesticide residues; or
- ☐ coming into (or near) an area where a pesticide has been used or deposited, and touching surfaces, breathing vapors in the air or by putting contaminated hands or objects in ones mouth.

What Exposures to People Does EPA Regulate?

The agency has developed a series of tools including models, databases, and guidance/reference documents that are used in

Pesticide Residue
- can be the original (known as the parent) chemical or can be a break-down product (such as a metabolite)

conjunction with chemical-specific information to conduct pesticide exposure assessments. The four basic kinds of exposures we currently look at include:

- ❑ Dietary Exposure from Food - how much pesticide residues we may receive through our daily diet;
- ❑ Drinking Water Exposure - how much pesticide residues we may receive through our drinking water. (It should be noted that not all pesticides are found in drinking water and this exposure analysis is conducted on a proportion of chemicals.);
- ❑ Occupational Exposure - how much pesticide residue we may receive directly from use at our places of work. (This is especially important for professional pesticide applicators in residential/agricultural settings and farmers.); and
- ❑ Residential Exposure - how much pesticide residues we may come in contact with beyond our diet and outside occupational settings, primarily in our homes and our lawns and gardens. Also included in this category are other general population exposures such as in schools, parks and daycare centers.

Residential Exposure

What is Residential Exposure?

EPA looks at residential exposure by assessing how a person could come in contact with the pesticide by:

- 1) using the pesticide in and around the home (home applicator) and
- 2) touching, breathing or ingesting (non-dietary) any residues that remain in and around the home after the pesticide is used (post-application).

The “home” is not limited to the inside of the actual building. Use of a pesticide on the property outside a home (such as use

EPA uses the term “residential exposure” to refer to any exposure to any person who lives in a home. This means children, as well as adults, are taken into consideration.

The term “home” means any domicile (apartment, house trailer, etc.), not just a single family dwelling.

Exposure Scenario - a description of a location and activity that leads to pesticide exposure.

Toxicity Endpoint
-A dose where no adverse effects are measured.

of a lawn pesticide product) is also considered a residential use; examples would be products that are used on pets, lawns or gardens.

How is a Residential Risk Assessment Conducted?

Addressing exposures to the general population, and particularly to children, is a complex task. Because of the many ways in which non-dietary residential exposures can occur, the agency has developed “Standard Operating Procedures (SOPs) for Residential Exposure Assessment” in order to add consistency and transparency to the risk assessment and regulatory process.

The SOPs were developed very shortly after the passage of FQPA and address over 40 different exposure scenarios. The SOPs provide guidance for our scientists to ensure consistency in the risk assessment process. The SOPs were developed using the most current data available and provide a “handbook” approach by presenting a description of each scenario with recommended algorithms, example calculations, a discussion of uncertainties and available references.

The first step in the risk assessment process identifies the uses of a pesticide from its registered label (such as use on lawns, use on carpets, crack and crevice, etc.) and how it’s applied (powder, spray, fogger, etc.).

Secondly, the pesticide’s toxicity is studied. EPA determines the most sensitive effect for each exposure route. A toxicity endpoint is ascertained for several exposure durations (such as acute , chronic, etc.).

Next, all appropriate exposure scenarios are determined. Examples of scenarios include:

- ☐ A toddler crawling on a treated lawn
- ☐ A person spraying a liquid pesticide
- ☐ A person working in a home garden
- ☐ A person living in a house treated for insects

A company may be required to conduct exposure studies that address specific exposure scenarios for an individual specific chemical. If an exposure study that addresses a specific exposure scenario has not been conducted, EPA scientists will use a model to evaluate available data, published literature, or some other source of information to develop a risk assessment for that scenario.

How Does EPA Assess a Residential Exposure for an Applicator?

EPA uses a model that focuses on those who directly handle or apply pesticide-containing products. The premise of this model is that exposure levels are related to the kind of equipment used during application (such as spray can, tractor-drawn sprayer, handheld garden sprayer); the physical form of the product (for example, liquid, powder, granules); and the kinds of clothing and equipment worn by the exposed individuals. EPA formally accepted this premise by including it in monitoring guidelines and initiating the development of a tool known as the Pesticide Handlers Exposure Database (PHED) in the mid 1980s.



Pesticide Handlers Exposure Database (PHED) -

A large database of actual pesticide exposure studies that EPA uses to estimate exposure when data are not available for a specific chemical exposure scenario.

From the beginning, PHED has been a collaborative task force effort on the part of EPA, the Canadian Pest Management Regulatory Agency, the California Department of Pesticide Regulation, and the pesticide industry. PHED contains the results of over 100 exposure studies completed using pesticides under actual use conditions. PHED was designed after intensive discussions involving exposure assessment experts, computer scientists, and statisticians. It was initially released in 1992. It is currently in use in many foreign countries (such as England, France, Australia, Japan) and throughout the industry. The program itself has been thoroughly evaluated as have all of the data in the system. The actual system and the monitoring techniques upon which the system is based have been “peer reviewed” (evaluated) by several scientific advisory committees over the years. This system is used to calculate exposures that are then coupled with pesticide use and cultural practice information to calculate exposures. Exposure is calculated by following formula:

Exposure = PHED Unit X Application X Area

Exposure Rate Treated

A dose can then be calculated from the exposure. When calculating a dose we adjust for body weight and the amount absorbed for both dermal and inhalation exposures.

How Does EPA Assess Residential Exposure for Post-Application Using a Model?

A second model focuses on those who are exposed to pesticides but who have not directly used them (i.e., post-application exposures). This exposure scenario would include a person harvesting in a home garden or a child playing on a pesticide-treated lawn. The premise of this model is that exposure levels are related to one's activity while in a previously treated area and the amount of pesticide available in that environment to the individual.

$$\text{Exposure} = \frac{\text{Transfer Coefficient} \times \text{Amount of Pesticide} \times \text{Duration}}{\text{Weight}}$$

The agency formally adopted this premise by publishing it in exposure monitoring guidelines as early as 1984. These kinds of exposure data are coupled with behavioral and environmental data (specific to individual chemicals) to calculate risks.

What is the Transfer Coefficient?

The transfer coefficient is similar to the PHED unit exposure used in applicator exposure assessments as described above. The transfer coefficient is calculated by the following formula:

$$\text{TC} = \frac{\text{Dermal Exposure}}{\text{Available Residue Concentration}}$$

Dermal exposure is determined by the exposure scenario. A monitoring study is conducted in order to determine how much exposure would occur over a given time.

For example, when calculating the transfer coefficient for exposure to children when they are playing on a pesticide treated lawn or carpet, we use the dermal exposure calculated

Dosimeter -
material used to
trap or collect
pesticide residues.



in the “Jazzercise™” monitoring study. Jazzercise™ is a type of aerobic dance exercise choreographed to music and is especially good as an exposure monitoring tool because it was designed to achieve maximum contact of the entire body with the ground. In the monitoring study participants wore special outfits containing dosimeters and performed the exercise routine for twenty minutes in an area treated with a known amount of pesticide. The dosimeters were then analyzed for the amount of pesticide that was transferred to them. An dermal exposure was then calculated. The Jazzercise™ monitoring study is useful because it is highly choreographed and its results can be reproduced. Reproducibility is very important in validating a scientific study because the study can be used with confidence by a variety of investigators. A study is said to be reproducible when can be repeated and the same results obtained.

How Realistic Are EPA Residential Exposure Assessments?

EPA’s residential exposure assessments are designed to be as realistic as possible. They are, however, generally conservative and this adds an extra measure of safety when regulating pesticides. When scientists have studied people in the real world (including the children of farmworkers) they have generally found a person’s exposure to be less than that predicted by our exposure assessments.

The conservative nature of our exposure assessments can be ascribed to several assumptions:

- ☐ We assume high amounts of pesticide residues will transfer to a person. Generally we assume 20-50% of the residues will transfer. Some techniques have shown that in some situations, only 1-3% of the residues are transferred. The highest reasonably possible transfer rate must be assumed for safety.
- ☐ We assume no residue dissipation. In other words, all the residues available initially, are available throughout the time a person is exposed. Dissipation rate is based on many factors (heat, sunlight, rain, etc.) so we must

include the conservative prospect that in a given case there is no residue dissipation.

- ❑ We assume that a person has no clothing on to protect themselves from exposure because little or no clothing is a possible realistic scenario in some circumstances.
- ❑ We assume 2 to 8 hours of continuous contact.

Development of Residential Exposure Assessment

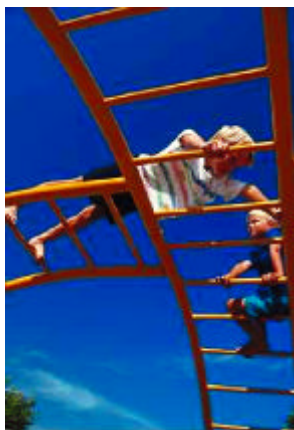
How Has EPA Developed Residential Exposure Data?

the Agency has always been proactive in addressing the residential exposure issue, particularly to children

Historically, the generation of post-application exposure data has been limited in comparison to the data available for handlers and generally has been intended to address farm worker issues. Nevertheless, the Agency has always been proactive in addressing the residential exposure issue, particularly to children. Beginning in the late 1980s, the Agency began to identify research needs in order to refine and better understand children's exposure. This effort culminated in the development of a research plan and several interactive workshops with academia, industry and other regulatory agencies in the 1990s. In 1995, realizing that additional data were required, the Agency issued two FIFRA Data Call-In Notices that specifically included requirements for the data needed to address farm worker issues and to address issues related to turf chemicals commonly illustrated by children playing on treated lawns. The difficulty of these tasks prompted the formation of two pesticide industry task forces each made up of about 40 companies with a total budget that will probably exceed \$50 million. The membership of these task forces represents a vast majority of the basic registrants in the pesticide industry. From the onset, the technical evolution of these task forces has been a collaborative effort between EPA, Health Canada, the California Department of Pesticide Regulation, and the pesticide industry members. In fact, a technical oversight committee exists that routinely meets to address research issues and progress. After the Food Quality Protection Act (FQPA) was enacted, several other task forces were also formed, or are in the process of forming, to address

Toxic Release Inventory (TRI)

- An EPA database containing information about releases and transfers of more than 650 toxic chemicals and compounds to the



residential exposure issues. The focus of these groups is to address indoor, residential issues and to develop a better understanding of residential pesticide use patterns. Agency representatives as well as representatives from academia and other regulatory agencies are also working very closely with these groups.

How Will EPA Further Improve Non-dietary Residential Exposure Assessment?

Exposure science is evolving rapidly and we are working diligently to make sure EPA's assessments are on the cutting edge. We are improving and refining our residential exposure assessments by:

- ☐ Expanding our evaluation of residential exposures to include playgrounds, schools, daycare centers, farmworker children in and around agricultural sites, etc.
- ☐ Funding and conducting research into exposure science. We are also reviewing available biomonitoring and health surveillance data to calibrate our existing assessments.
- ☐ Revising our SOPs to increase realism (such as determining a realistic transfer rate).
- ☐ Identifying the range of exposure variables where available. For example, the amount of time spent on a lawn. Instead of using an average, we would look at the range of time a person might spend on a lawn.
- ☐ Identifying exposure scenarios which are not a direct consequence of pesticide use (e.g. releases from facilities as reported in the Toxic Release Inventory (TRI)).

How Will Task Force Data Be Used?

Data are being developed by several task forces to develop better exposure assessments. These data are, however, proprietary data and generally can only be used in exposure

environment. TRI stores release-transfer data hierarchically by facility, by year and chemical, and by medium of release (air, water, underground injection, land disposal, and offsite).

assessments to support chemicals that are manufactured by companies that are a members of the task force or otherwise entitled to use the data.